K110337

510(k) Summary
January 11, 2011

MAR 16 2012

Contact Person: David D. Dalise
President/ Owner
OCO Biomedical, Inc.
8500 Washington St. N.E., Suite A-1
Albuquerque, NM 87113
Phone: (505) 293-0025

Trade Name: I Macro Implant System
Common Name: Dental Implant
Classification Name: Dental Implant Endosseous, Root-Form

Substantial Equivalence to:

Immediate Stabilizing Implant (ISI)	K033392 (Cleared 12/11/03)
OCO 5.0mm Taper Implant	K023336 (Cleared 10/9/02)
OCO Biomedical TSI & ERI	K090174 (Cleared 9/14/09)
Mega Gen	K081302 (Cleared 8/15/08)
Implant Direct	K061319 (Cleared 9/29/06)
Southern Implants	K071161 (Cleared 11/16/07)

Description of Device:

The I Macro implants are self-tapping; commercially pure; Titanium Alloy threaded screws, with light grit blasting or roughened surface treatment. These materials and procedures are exactly the same as cleared in the OCO Biomedical submission K090174. The I Macro Implant is available in a 6.0, 7.0, 8.0 & 9.0mm diameter and is available in 8, 10, and 12mm lengths.

Titanium Chemical Compositions:

6AL/4V ELI
Carbon - 0.08%
Vanadium – 3.5%-4.5%
Nitrogen - 0.05%
Aluminum – 5.5%-6.5%
Oxygen - 0.013
Hydrogen - 0.015%
Iron - 0.25%
Titanium – Balance

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The compatible abutments for the I Macro Implants where cleared under 510 K090174.
Abutment Unit Numbers:

- 4 CB 5.5 TSI
- 4 IOT 0 TSI
- 4100 TSI
- 5150 TSI
- 4200 TSI
- 5250 TSI

(Please see Abutment Attachment)

Indications for Use:

The I Macro Implant system is intended for implantation in the mandibular molar region where bone exists and the surgeon has determined that placement of a narrower diameter implant would increase the chance of failure due to poor primary stability, or increased surgical procedures leading to complications. This I Macro implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or complete arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with proper occlusal loading, to restore the chewing function.

Substantial Equivalence:

OCO Biomedical, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the I Macro Implants are substantially equivalent in indications and design principles to predicate devices previously cleared by the FDA: Immediate Stabilizing Implant (ISI) K033392 (Cleared 12/11/03), OCO Biomedical 5.0mm Taper Implant K023336 (Cleared 10/9/02), Mega Gen K081302 (Cleared 8/15/2008),OCO Biomedical TSI ERI K090174 (Cleared 9/14/09), Implant Direct K061319 (Cleared 9/29/06) and Southern Implants K071161 (Cleared 11/16/07).

The I Macro Implant has the following similarities to the predicate devices:

-has the same intended use
-incorporates the same materials and design
-is packaged and sterilized using the same materials and processes

Summary of Technological Comparison:

The fundamental scientific technology of the device is identical or very similar to referenced predicate devices, including materials, processing, packaging, and sterilization methods. See comparison table in the Executive Summary section of this application.

Fatigue testing was conducted according to ISO 14801, biocompatibility testing was conducted according to ISO 10993-5 and ISO 10993-1 and SEM analysis of the implant surface after RBM blasting and acid etching.

Conclusion:

OCO Biomedical, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the I Macro Implants are substantially equivalent in indications and design principles to predicate devices previously cleared by the FDA.

Standards to which OCO Biomedical claims compliance:

- ISO 14801:2007, Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- ISO 10993-1:2009, Biological evaluation of medical devices - part 1: evaluation and testing
- ISO 868-5:2009, Packaging materials and systems for medical devices which are to be sterilized; Part 5: Self-sealable pouches and reels of paper and plastic film construction; Requirements and test methods
- ISO 11607-1:2009, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F 1980:2007, Standard guide for accelerated aging of sterile medical device packages
- ISO 11137-1:2006, Sterilization of health care products – Radiation Part 1: Requirements for development, validation, routine control of a sterilization process for medical devices.
- ISO 11137-2:2007, Sterilization of health care products – Radiation Part 2: Establishing the sterilization dose.
- ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 1041:2008, Information supplied by the manufacturer with medical devices
- ISO 980:2008, Graphical symbols for use in the labelling of medical devices
- ISO 15223:2007, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 14155-1:2003, Clinical investigation of medical devices for human subjects - Part 1: General requirements
- ISO 1041:2008 Information supplied by the manufacturer of medical devices

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- ISO 11137–3 Sterilization of health care products – Radiation

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ISO 10993-5:2009 Biological evaluation of medical devices

- ISO 10993-5:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

- ISO 10993-11:2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

- ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

- ISO 11607 Packaging for Terminally Sterilized Medical Devices
- EN 868-5:2009 Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jack Bloom
Regulatory Manager
OCO Biomedical
8500 Washington Street, NE
Suite A-1
Albuquerque, New Mexico 87113

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Re: K110337
Trade/Device Name: I Macro Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 10, 2012
Received: March 12, 2012

Dear Mr Bloom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K110337**

Device Name: I **Macro Implant System**

Indications for use:

The I Macro Implant system is intended for implantation in the mandibular molar region where bone exists and the surgeon has determined that placement of a narrower diameter implant would increase the chance of failure due to poor primary stability, or increased surgical procedures leading to complications. This I Macro implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or complete arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with proper occlusal loading, to restore the chewing function.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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